SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

AUG 19 2009

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1. **DEVICE NAME (Trade/common, and classification):**

Proprietary name: K-LASER

Common/usual name: K-1200

Classification name: Therapy Probe.

Classification: Class II

Regulation Nos.: 890.5500

Product Codes: ILY

2. PREDICATE DEVICES:

K-LASER – Cleared under K050070

LCT-1000 – Cleared under K070400

3. PERFORMANCE STANDARDS:

K-1200 conforms to the applicable requirements of 21 CFR section 1010 (Performance Standards for Electronic Products: General) and 21 CFR sections 1040.10 and 1040.11 (Performance Standards for Light-Emitting Products).

4. DESCRIPTION:

K-1200 is an infrared therapy table device, easy to transport, usable also without electrical net, thanks to a battery pack. It is composed of a touch screen for managing all the device functions, an emitter, an handpiece for the delivery of light, software and an on/off button to activate and deactivate the infrared emission.

5. INTENDED USE/ INDICATIONS FOR USE:

The device is indicated for emitting energy in the Infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

The intended Use/Indications For Use stated herein are identical to the cleared indications for the predicate device.

6. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE:

K-1200 generates infrared therapy for treatment of selected medicals conditions and shares the same basic characteristics and the same intended use as the predicate device. Therefore, the proposed device is substantially equivalent to the K-LASER, cleared under K050070 and LCT-1000, cleared under K070400.

7. SAFETY AND EFFECTIVENESS:

There are no substantive differences between the product defined in this 510(k) submission and the predicate device. They are similar to the technologies that are currently used in other similar medical devices. They were developed and documented under Eltech's mature Quality Managerment System, under The Quality System Regulation, 21 CFR Part 820, under design/change control, and verified/validated to applicable standards/guidance documents. Besides, Eltech's Quality Assurance System is certified by CERMET, notified body n. CE 0476, according to Annex II of 93/42 EEC Directive, transposed in Italy by Dlgs. n. 46 of 24 February 1997.

K-1200 is safe and effective when used as indicated in specific applications under a clinician's supervision/therapy program.

Signed: _____ Date: 14 May, 2009

Eltech s.r.l.
Francesco Zanata
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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AUG 19 2009

Re: K091497
Trade/Device Name: K-1200
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: July 2, 2009
Received: July 21, 2009

Dear Dr. Albright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091497

510(K) PREMARKET SUBMISSION	510(K) K-1200 HEAT LAMP SECTION_4: STATEMENT OF INDICATION FOR USE	Rev. 0 Sec. 4 Page 1 of 1

INDICATIONS FOR USE

Device Name: **K-1200**

Indications for Use:

The device is indicated for emitting energy in the Infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(K) Submission 510(k) Number K091497